

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

ZINO DAVIDOFF SA,

Plaintiff,

v.

CVS CORPORATION,

Defendant.

06 Civ. 15332 (KMK)

**DECLARATION OF DR. HANS-JÜRGEN WEISSGRAEBER IN SUPPORT OF
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

I, Dr. Hans-Jürgen Weissgraeber, hereby declare as follows:

1. I am the Vice President for Regulatory Affairs and Quality Assurance International at Coty GmbH in Mainz, Germany. Coty GmbH is an affiliate of Coty Inc. Coty Inc. indirectly owns Lancaster BV, the exclusive fragrance licensee of Plaintiff Zino Davidoff SA ("Zino Davidoff"). Coty Inc. also owns Coty Prestige US LLC, the authorized U.S. distributor of DAVIDOFF fragrances (Coty Prestige Lancaster Group GmbH, Coty GmbH, Coty Inc, Lancaster BV and Coty Prestige US LLC collectively referred to as "Coty Prestige"). I am in charge of Coty Prestige's worldwide quality assurance program, including the U.S. and responsible for ensuring that we are in compliance with all applicable laws and regulations.

2. I have been with Coty GmbH for approximately fifteen years, and for that entire time, have worked in the Quality Assurance division. For the last five years, I have also been the head of Coty Prestige's Regulatory Affairs division. I have a Ph.D. in chemistry and prior to joining Coty Prestige I worked in the pharmaceutical field in quality assurance.

3. I submit this declaration based upon my own personal knowledge in support of the motion of Zino Davidoff SA ("Zino Davidoff") for a preliminary injunction.

**I. The Production Code System Anchors Zino Davidoff's
And Coty Prestige's Worldwide Quality Assurance Program**

4. Zino Davidoff and Coty Prestige exercise strict quality control over their fragrance products, including but not limited to DAVIDOFF COOL WATER, on a global basis. We do this for a number of reasons, including but not limited to (i) protecting the consumer given the nature of the product and the potential public health and safety risks and (ii) ensuring compliance with governmental regulations and directives.

5. As part of our worldwide quality assurance measures, we have developed and implemented a coding system for our fragrance products whereby we apply either a unique numeric production code (the Production Code system") or a numeric batch code (the "Batch Code system") to each unit to permit us to trace and resolve quality issues. While the Batch Code system is an effective means of quality assurance, our Production Code system, which provides full traceability by individual unit, allows us to achieve an even higher level of quality assurance than the Batch Code system.

6. We use the Production Code system rather than the Batch Code system for most of our DAVIDOFF COOL WATER fragrances because they are more frequently counterfeited than some of our other fragrances and because consumers expect the absolute best from our luxury brands. Because the Production Code system provides such a high degree of quality assurance, as well as other benefits, we are planning to increase our use of this coding system on other fragrance brands, such as Calvin Klein, despite the considerable cost of doing so.

7. There are three main quality assurance areas that we focus on regarding fragrance products, namely the packaging, the formula and the production itself. To ensure that we continue to produce high-quality perfume products across our portfolio of fragrance brands, our quality assurance divisions have created and implemented numerous quality assurance measures.

Since its inception, the Production Code system has become vitally important to the quality assurance strategy for our prestige brands.

A. The Production Code System Is Vital To Protecting The High Quality Of DAVIDOFF COOL WATER Fragrance Products

8. Among the bedrock concepts of our quality assurance strategy for DAVIDOFF COOL WATER fragrances is full traceability of each unit across the production and distribution chains. Full traceability helps us identify and rectify possible quality issues with our fragrance products. Usually, a notice or complaint from a retailer, distributor, consumer or employee will trigger these investigations. Upon receiving notice of a possible product defect, we immediately attempt to determine the exact Production Code(s) affixed to the fragrance product unit(s) at issue.

9. The Production Code, and the full traceability provided by it, allows us to determine whether in fact there is a quality issue and to investigate the entire production and distribution chains for each fragrance unit possibly affected. If there is a quality issue, it enables us to pinpoint exactly where and when it arose and what other units are affected, if any, in our distribution chain. Because the Production Code enables us to keep in our database a variety of data on each and every unit bearing the unique Production Code, we normally accomplish these investigations extremely efficiently and in a short period of time, thereby allowing us to identify the cause, contain any suspect product and protect the health and safety of consumers in a very short period of time.

10. There are many examples of our use of the Production Code to investigate and take corrective action regarding a quality issue with our fragrance products. I list below just a few representative examples:

a. In or around October 2001, we received a customer complaint regarding an under-filled bottle of DAVIDOFF COOL WATER eau de toilette. We used the Production Code to investigate the fill level of that precise unit of DAVIDOFF COOL WATER, and other units of DAVIDOFF COOL WATER filled on that filling line on that date. We determined that no anomaly existed as to the filling weight of that unit.

b. In or around August 2003, we received a complaint regarding bottles of DAVIDOFF ECHO eau de toilette packaged in the wrong box. We used the unique Production Code to trace the defective product and determined that a problem on a single production line caused the error and that there was only a single carton with the improperly boxed product. We then found and retrieved the units within that carton, again using the Production Code.

c. In or around August 2003, we received a complaint regarding a bottle of JIL SANDER SUN eau de toilette that exploded on a store shelf. We used the Production Code of the exploded bottle to trace the unit, look at the fill data in our Production Code records, and determined that overfilling had caused the bottle to explode, and that the overfill occurred at one filling line. We then used the Production Code to trace the other bottles of JIL SANDER SUN filled on that filling line on the same date, and withdrew those units from the respective warehouses, distributors and retailers. In all, we withdrew approximately three hundred and twenty-two (322) bottles of defective product due to overfill.

d. In or around February 2002, we received information regarding under-filled bottles of JIL SANDER SENSATIONS perfume. We used the Production Code to determine what filling lines and during what times the problem occurred. We then used the Production Code to determine the extent of the under-fill issue, and discovered over 6,600 under-filled units.

We also used the Production Code to trace where these 6,600 units were in the distribution chain, blocked their shipment to distributors and returned the defective units to the factory.

e. In or around November 1997, we received complaints regarding defective dispensers on certain units of JOOP! WHAT ABOUT ADAM eau de toilette. We used the Production Code to determine the production lines involved and when the problem occurred. We then used the Production Code to find and separate the defective units from the others, thereby blocking the defective units from shipping to Coty Prestige's customers.

11. Without our Production Code system, such accurate, targeted investigations and recalls would be nearly impossible. I have no doubt that without our Production Code system a greater number of non-compliant products would have reached consumers.

12. Because of our Production Code system and the full traceability it affords, our quality assurance investigations allow us to determine the root causes of the quality issues on our fragrance products. It allows us to address quality assurance issues proactively in addition to reactively, and to implement necessary changes to correct issues in our production and/or distribution chains. The Production Code system is a major tool in our efforts to assure the highest possible quality in our prestige fragrance products.

13. While some of the above examples of quality issues with our fragrance products concerned thousands of units, we have thankfully never had a situation where we needed to conduct a mass recall for any of our fragrance products. I attribute this in large part to the extremely high quality assurance standards that we insist upon for all our fragrance brands. However, we certainly need to be prepared for the contingency that some day we may need to recall product due to the implementation of a new governmental regulation on ingredients or the discovery of a product defect we did not realize at the time of manufacture. Because of the

Production Code system and full traceability afforded by it, we could in many situations avoid a mass recall of all product by pinpointing exactly where the potentially defective products are located in the production and distribution chains. Whether it is ten units, a hundred units or ten thousand units, our quality assurance investigations and recall system work the exact same way, with the Production Code allowing us to investigate and address any quality issues efficiently and effectively and with considerable precision.

B. The Production Code Enables Zino Davidoff And Coty Prestige To Comply With Government Regulations And Directives

14. We distribute our fragrance products, including DAVIDOFF COOL WATER, throughout the world. We must therefore comply with varying governmental regulations and directives that specifically address quality assurance issues. Because our quality assurance program is worldwide, consumers in jurisdictions with less governmental regulation benefit from the more stringent regulation elsewhere.

15. While at this point there is no federal or state requirement in the U.S. requiring us to affix unique Production Codes to fragrance products, the State of California does have a product dating requirement for fragrances, among other products. Specifically, California Administrative Code Title 17, Section 94512 requires that we clearly display on each unit of fragrance product the day, month and year on which we manufactured it. Annexed hereto as Exhibit 1 is a true and correct copy of California Administrative Code Title 17, Section 94512. Section 94512 specifically allows us to substitute a code instead of merely affixing the date, as long as it complies with the requirements set forth in Section 94512. Our Production Code complies with this requirement. Because we use a unique code indicating the date of manufacture, Section 94512 requires that we file an explanation of our Production Code with the Executive Officer of the Air Resources Board on an annual basis. We are currently in full

compliance with California's coding requirement -- putting aside the potential issue of our being found out of compliance due to the possible distribution and sale of decoded products by CVS and others in California.

16. Section 94512 also states that "no person shall erase, alter, deface, or otherwise remove or make illegible any date or code indicating the date of manufacture from any regulated product container without the express authorization of the manufacturer." We have never authorized any person or entity to remove our Production Code or make it illegible.

17. The European Union ("EU") in the past has issued directives restricting or banning the use of certain ingredients in fragrances and cosmetics. Typically, such an EU directive will provide stop dates after which we cannot ship the fragrance products containing the ingredients at issue and after which the retailer cannot sell these fragrance products. For example, the Commission of the European Communities Directive 2002/34/EC bans certain ingredients when used with fragrances and Directive 2004/88/EC restricts the use of a certain ingredient when used with fragrances. Annexed hereto as Exhibit 2 and Exhibit 3 respectively are Commission Directives 2002/34/EC and 2004/88/EC. The Production Code system, and its full traceability, affords us the best and most efficient way to comply fully with directives such as these. Without our Production Code, it would be exceedingly difficult to locate each and every unit of fragrance at issue and would run the risk of failing to comply with the directive.

18. As noted in Paragraph 15 above, although there may not be analogous regulations in the U.S., U.S. consumers get the benefit of our compliance with the EU Directives under our quality assurance system. Further, industry groups in the U.S. are advocating increased regulation to insure public health and safety. The Cosmetic, Toiletry, and Fragrance Association ("CTFA") has proposed coding requirements that allow for traceability to manufacturing and distribution records, which is exactly what our Production Code allows us to do. Annexed hereto as Exhibit 4 are true and correct copies of relevant pages of the CTFA's Draft Guidelines for Cosmetic Good Manufacturing Practices. The CTFA, in its Labeling Manual, also sets forth the benefits of a batch coding requirement, namely that batch codes serve as an easy means of identification should a recall or investigation be required. Annexed hereto as Exhibit 5 are true and correct copies of the relevant pages of the CTFA Labeling Manual.

19. While batch coding requirements are not yet mandatory for fragrances in the U.S., they are mandatory for pharmaceuticals. As discussed in Paragraph 5 above, our Production Code system is even better than a batch code system, as again, it allows us to maintain information on and to track each individual unit, making investigations and recalls even easier.

II. CVS's Sale of Decoded Gray Market DAVIDOFF Products Is Causing Zino Davidoff Severe And Irreparable Harm

20. CVS's sale of decoded gray market DAVIDOFF COOL WATER fragrances has damaged our quality assurance program by making it far more difficult, if not impossible, to trace the source of any quality issues that may arise with respect to those units.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Date: Mainz, Germany
April 5, 2007

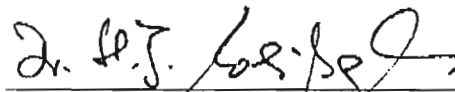

Dr. Hans-Jürgen Weissgräber

EXHIBIT 1

Westlaw.

17 CA ADC § 94512

17 CCR s 94512

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C**BARCLAYS OFFICIAL CALIFORNIA CODE
OF REGULATIONS****TITLE 17. PUBLIC HEALTH****DIVISION 3. AIR RESOURCES****CHAPTER 1. AIR RESOURCES BOARD****SUBCHAPTER 8.5. CONSUMER PRODUCTS****ARTICLE 2. CONSUMER PRODUCTS**This database is current through 02/09/07, Register
2007, No. 6

s 94512. Administrative Requirements.

(a) Most Restrictive Limit.

(1) Products Manufactured Before January 1, 2007, and FIFRA-registered Insecticides Manufactured Before January 1, 2008. Notwithstanding the definition of "product category" in Section 94508, if anywhere on the principal display panel of any consumer product manufactured before January 1, 2007, or any FIFRA-registered insecticide manufactured before January 1, 2008, any representation is made that the product may be used as, or is suitable for use as a consumer product for which a lower VOC limit is specified in Section 94509(a), then the lowest VOC limit shall apply. This requirement does not apply to general purpose cleaners and insecticide foggers.

(2) Products Manufactured on or After January 1, 2007, and FIFRA-registered Insecticides Manufactured on or After January 1, 2008. Notwithstanding the definition of "product category" in Section 94508, if anywhere on the container or packaging of any consumer product manufactured on or after January 1, 2007, or any FIFRA-registered insecticide manufactured on or after January 1, 2008, or on any sticker or label affixed thereto, any representation is made that the product may be used as, or is suitable for use as a consumer product for which a lower VOC limit is specified in Section 94509(a), then the lowest VOC limit shall apply. This requirement does not apply to general purpose cleaners and insecticide foggers.

(3) Rules that Apply when a Product Category Definition Excludes Other Product Categories.

If a definition of a regulated product category in section 94508(a) states that the product category "does not include" one or more other product categories, the "most restrictive limit" provisions of section 94512(a) apply to regulated products that meet the definition of the regulated product category and also make any representation that the regulated product may be used as (or is suitable for use as) a product that falls within one or more of the excluded product categories.

For example, if the definition for Regulated Product Category A states that it "does not include" Regulated Product Category B, then the "most restrictive limit" provisions apply to a regulated product that meets the definition of Regulated Product Category A, but also makes a representation that it may be used as (or is suitable for use as) Regulated Product Category B. In other words, if the regulated product makes any representation that it may be used as (or is suitable for use as) Regulated Category Product B, then the regulated product would be subject to the lowest VOC limit specified in section 94509(a) for either Product Category A or Product Category B.

For the purposes of this section:

"Regulated product" means a consumer product for which a VOC standard is specified in section 94509(a), and

"Representation" has the same meaning as used above in subsections 94512(a)(1) and 94512(a)(2) (i.e., what statements qualify as a "representation" depends on the date the product was manufactured and whether the statements appear on the "principal display panel" or other parts of the product container or packaging.)

(b) Product Dating.

(1) Each manufacturer of a consumer product subject to Section 94509 shall clearly display on each consumer product container or package, the day, month, and year on which the product was manufactured, or a code indicating such date.

(2) A manufacturer who uses the following code to indicate the date of manufacture shall not be subject to the requirements of section 94512(c)(1), if the code is represented separately from other codes on the product container so that it is easily recognizable:

YY DDD = year year day day day

Where: "YY" = two digits representing the year in which the product was manufactured, and

"DDD" = three digits representing the day of the year on which the product was manufactured, with "001" representing the first day of the year, "002" representing the second day of the year, and so forth (i.e. the "Julian date")

(3) This date or code shall be displayed on each consumer product container or package no later than twelve months prior to the effective date of the applicable standard specified in section 94509.

(4) Except as otherwise provided in subsection (b)(5), for products manufactured on or after January 1, 2006, the date or code shall be displayed on the product container such that it is readily observable without irreversibly disassembling any portion of the product container or packaging. For the purposes of this subsection, information may be displayed on the bottom of a container as long as it is clearly legible without removing any product packaging.

(5) Products Sold in Multi-unit Packages.

(A) Products sold, supplied, or offered for sale in multi-unit packages are not required to comply with subsection (b)(4).

(B) If a multi-unit package does not comply with subsection (b)(4), the "sell-through" provisions of section 94509(c)(1) shall not apply to the individual product units contained within the multi-unit package. In other words, if any multi-unit package produced or assembled after January 1, 2006, does not display the date(s) or date-code(s) of the product units, such that the displayed information is readily observable without irreversibly disassembling any

portion of the container or packaging, the individual product units shall be subject to the VOC standards in effect when the multi-unit package is sold, supplied, or offered for sale, regardless of the date on which the product units were manufactured.

(C) A multi-unit package may comply with subsection (b)(4) by displaying the date of assembly instead of the date(s) or date-code(s) of the individual product units, so long as the date of assembly is readily observable without irreversibly disassembling any portion of the container or packaging. The "date of assembly" means the date that the individual product units are assembled into the finished multi-unit package. If the date of assembly is displayed instead of the individual date(s) or date-code(s), the "date of assembly" shall be the "date of manufacture" for all of the product units contained within the multi-unit package. In other words, all of the product units shall be deemed to have been manufactured on the date these units are assembled into the multi-unit package, even if the individual product units show different date(s) or date-code(s), and the "date of assembly" shall be "date of manufacture" of each product unit for the purposes of applying the "sell-through" provisions of section 94509(c).

(6) The requirements of this subsection (b) shall not apply to:

(A) personal **fragrance** products of 2 milliliters or less, which are offered to consumers free of charge for the purpose of sampling the product; or

(B) products containing no VOCs (as defined in section 94508), or containing VOCs at 0.10% by weight or less.

(c) Additional Product Dating Requirements

(1) If a manufacturer uses a code indicating the date of manufacture, for any consumer product subject to section 94509 an explanation of the code must be filed with the Executive Officer of the ARB no later than twelve months prior to the effective date of the applicable standard specified in section 94509. Thereafter,

17 CA ADC § 94512
 17 CCR s 94512
 Cal. Admin. Code tit. 17, s 94512

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manufacturers using a code must file an explanation of the code with the Executive Officer on an annual basis, beginning in 2006. The explanation of the code must be received by the Executive Officer on or before January 31st of each year, with the first explanation due on or before January 31, 2006.

(2) If a manufacturer changes any code indicating the date of manufacture for any consumer product subject to subsection (c)(1), an explanation of the modified code must be received by the Executive Officer before any products displaying the modified code are sold, supplied, or offered for sale in California.

(3) No person shall erase, alter, deface, or otherwise remove or make illegible any date or code indicating the date of manufacture from any regulated product container without the express authorization of the manufacturer.

(4) Codes indicating the date of manufacture are public information and may not be claimed as confidential.

(d) Additional Labeling Requirements for Aerosol Adhesives, Adhesive Removers, Electronic Cleaner, Electrical Cleaner, Energized Electrical Cleaner, and Contact Adhesives.

(1) In addition to the requirements specified in subsections (a), (b) and (c), both the manufacturer and responsible party for each aerosol adhesive, adhesive remover, electronic cleaner, electrical cleaner, energized electrical cleaner, and contact adhesive product subject to this article shall ensure that all products clearly display the following information on each product container which is manufactured on or after the effective date for the category specified in section 94509(a):

(A) The product category as specified in section 94509(a) or an abbreviation of the category shall be displayed;

(B) 1. The applicable VOC standard for the product is specified in section 94509(a), except for Energized Electrical Cleaner,

expressed as a percentage by weight, shall be displayed unless the product is included in an alternative control plan approved by the Executive Officer, as provided in Article 4, Sections 94540-94555, Title 17, California Code of Regulations, and the product exceeds the applicable VOC standard;

2. If the product is included in an alternative control plan approved by the Executive Officer, and the product exceeds the applicable VOC standard specified in section 94509(a), the product shall be labeled with the term "ACP" or "ACP product;"

(C) If the product is classified as a special purpose spray adhesive, the applicable substrate and/or application or an abbreviation of the substrate/application that qualifies the product as special purpose shall be displayed;

(D) If the manufacturer or responsible party uses an abbreviation as allowed by this subsection 94512(d), an explanation of the abbreviation must be filed with the Executive Officer before the abbreviation is used.

(2) The information required in section 94512(d)(1), shall be displayed on the product container such that it is readily observable without removing or disassembling any portion of the product container or packaging. For the purposes of this subsection, information may be displayed on the bottom of a container as long as it is clearly legible without removing any product packaging.

(3) No person shall remove, alter, conceal, or deface the information required in section 94512(d)(1) prior to final sale of the product.

Note: Authority cited: Sections 39600, 39601 and 41712, Health and Safety Code. Reference: Sections 39002, 39600, 40000 and 41712, Health and Safety Code.

HISTORY

17 CA ADC § 94512
17 CCR s 94512
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1. New section filed 9-19-91; operative 10-21-91 (Register 92, No. 12).
2. Amendment filed 12-7-92; operative 1-6-93 (Register 92, No. 50).
3. Amendment filed 11-18-97; operative 11-18-97 pursuant to Government Code section 11343.4(d) (Register 97, No. 47).
4. Amendment of subsections (b), (b)(2) and (c) filed 7-17-98; operative 8-16-98 (Register 98, No. 29).
5. New subsections (d)-(d)(3) filed 4-18-2001; operative 5-18-2001 (Register 2001, No. 16).
6. Amendment filed 6-20-2005; operative 7-20-2005 (Register 2005, No. 25).
17 CCR s 94512, 17 CA ADC s 94512

ICAC

17 CA ADC s 94512
END OF DOCUMENT

EXHIBIT 2

TWENTY-SIXTH COMMISSION DIRECTIVE 2002/34/EC

of 15 April 2002

adapting to technical progress Annexes II, III and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

substances for other uses is being carried out by the SCCNFP.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ⁽¹⁾, as last amended by Commission Directive 2000/41/EC ⁽²⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP),

Whereas:

(1) Entry 293 of Annex II includes radioactive substances among the substances prohibited in cosmetic products. However, footnote 1 to entry 293 allows, under the conditions set out therein, the presence of natural radioactive substances and of radioactive substances caused by artificial contamination from the environment by making reference to Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation ⁽³⁾. These Directives were repealed by Council Directive 96/29/Euratom ⁽⁴⁾, Article 6(5) thereof providing that Member States shall permit neither the deliberate addition of radioactive substances in the production of cosmetic products nor the import and export of such goods. Directive 96/29/Euratom also provides for the definition of radioactive substances for the purpose of its application. Therefore, entry 293 of Annex II should be amended accordingly.

(2) On the basis of IFRA (International Fragrance Association) Code of Practice, the SCCNFP has listed 36 substances that must not form part of fragrance compounds used in cosmetic products. Of these 36 fragrance ingredients, seven are already included in Annex II and one (6-methylcoumarin) under reference No 46 in Annex III, Part 1, which already restricts its use to oral hygiene products. Therefore the 28 remaining fragrance ingredients should be included in the list of Annex II. The safety of these substances has only been assessed by the SCCNFP for their use as fragrance ingredients. Accordingly, it is necessary to regulate their use for this purpose. Further safety assessment of these

(3) The SCCNFP recommends that methyleugenol should not be intentionally added as a cosmetic ingredient. Therefore methyleugenol should be included in Annex II. As methyleugenol is however naturally present in essential oils that are used as components in cosmetic products, the SCCNFP has set specific maximum concentrations when present in cosmetic products.

(4) On the basis of information on the use in cosmetic products of lithium hydroxide and calcium hydroxide and their safety evaluation, the SCCNFP recommends that their use should be restricted. Therefore entries 15b and 15c of Annex III, Part 1, should be amended accordingly.

(5) On the basis of a toxicological evaluation, the SCCNFP recommends that the maximum residual acrylamide content needs to be restricted in the finished product. Therefore, polyacrylamide should be included in Annex III, Part 1.

(6) The SCCNFP has made toxicological evaluations of 61 hair dyes, including recommendations on their field of application, maximum concentration levels and specific warnings. One is already included under reference No 16 in Annex III, Part 1, which shall therefore be amended. More information on the safety of some hair dyes is still needed, in particular in order to investigate a potential link between long term regular use of permanent hair dyes and an increased risk for bladder cancer, as requested by the SCCNFP. Therefore the 60 remaining hair dyes should be included in Annex III, Part 2. Entry 8 of Annex III, Part 1, covers a group of phenylendiamine derivatives used as hair dyes. In order to avoid double entries, the text in column b should be amended to except those derivatives listed elsewhere in Annex III.

(7) The SCCNFP recommends that musk xylene can be safely used in cosmetic products, excluding oral care products, up to a maximum daily theoretically absorbed dose of about 10 µg/kg/day. Therefore, until the risk assessment of this substance in the framework of Council Regulation (EEC) No 793/93 ⁽⁵⁾ on the evaluation and control of the risks of existing substances is finalised, musk xylene should be included in Annex III, Part 2.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169.

⁽²⁾ OJ L 145, 20.6.2000, p. 25.

⁽³⁾ OJ 11, 20.2.1959, p. 221/59.

⁽⁴⁾ OJ L 159, 29.6.1996, p. 1.

⁽⁵⁾ OJ L 84, 5.4.1993, p. 1.

- (8) The SCCNFP recommends that musk ketone can be safely used in cosmetic products, excluding oral care products, up to a maximum daily theoretically absorbed dose of about 14 µg/kg/day. Therefore, until the risk assessment of this substance in the framework of Regulation (EEC) 793/93 is finalised, musk ketone should be included in Annex III, Part 2.
- (9) The SCCNFP has expressed the opinion that the UV-filter dimethicodiethylbenzalmalonate can be safely used in cosmetic products under certain restrictions. Therefore, dimethicodiethylbenzalmalonate should be included in Annex VII, Part 1.
- (10) The SCCNFP has expressed the opinion that titanium dioxide can be safely used as UV-filter in cosmetic products under certain restrictions. Therefore, titanium dioxide should be included in Annex VII, Part 1.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is hereby amended as indicated in the Annex to this Directive.

Article 2

Member States shall take the necessary measures to ensure that cosmetic products containing the substances listed in Annexes II, III and VII to Directive 76/768/EEC, as set out in the Annex

to this Directive, which are supplied to the final consumer after 15 April 2004, comply with the provisions of this Directive.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 April 2003 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the third day following its publication in the *Official Journal of the European Communities*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 15 April 2002.

For the Commission

Erkki LIIKANEN

Member of the Commission

ANNEX

Annexes II, III and VII to Directive 76/768/EEC are amended as follows:

1. In Annex II:

(i) Reference No 293 and corresponding footnote 1 are replaced by the following:

'293. Radioactive substances, as defined by Directive 96/29/Euratom (1) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

(1) OJ L 159, 29.6.1996, p. 1.'

(ii) Reference Nos 423 to 451 are added as indicated below:

'423. Alanroot oil (*Inula helenium*) (CAS No 97676-35-2), when used as a fragrance ingredient.

424. Benzyl cyanide (CAS No 140-29-4), when used as a fragrance ingredient.

425. Cyclamen alcohol (CAS No 4756-19-8), when used as a fragrance ingredient.

426. Diethyl maleate (CAS No 141-05-9), when used as a fragrance ingredient.

427. Dihydrocoumarine (CAS No 119-84-6), when used as a fragrance ingredient.

428. 2,4-Dihydroxy-3-methylbenzaldehyde (CAS No 6248-20-0), when used as a fragrance ingredient.

429. 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) (CAS No 40607-48-5), when used as a fragrance ingredient.

430. 4,6-Dimethyl-8-*tert*-butylcoumarin (CAS No 17874-34-9), when used as a fragrance ingredient.

431. Dimethyl citraconate (CAS No 617-54-9), when used as a fragrance ingredient.

432. 7,11-Dimethyl-4,6,10-dodecatrien-3-one (CAS No 26651-96-7), when used as a fragrance ingredient.

433. 6,10-Dimethyl-3,5,9-undecatrien-2-one (CAS No 141-10-6), when used as a fragrance ingredient.

434. Diphenylamine (CAS No 122-39-4), when used as a fragrance ingredient.

435. Ethyl acrylate (CAS No 140-88-5), when used as a fragrance ingredient.

436. Fig leaf absolute (*Ficus carica*) (CAS No 68916-52-9), when used as a fragrance ingredient.

437. *trans*-2-Heptenal (CAS No 18829-55-5), when used as a fragrance ingredient.

438. *trans*-2-Hexenal diethyl acetal (CAS No 67746-30-9), when used as a fragrance ingredient.

439. *trans*-2-Hexenal dimethyl acetal (CAS No 18318-83-7), when used as a fragrance ingredient.

440. Hydroabietyl alcohol (CAS No 13393-93-6), when used as a fragrance ingredient.

441. 6-Isopropyl-2-decahydronaphthalenol (CAS No 34131-99-2), when used as a fragrance ingredient.

442. 7-Methoxycoumarin (CAS No 531-59-9), when used as a fragrance ingredient.

443. 4-(4-Methoxyphenyl)-3-butene-2-one (CAS No 943-88-4), when used as a fragrance ingredient.

444. 1-(4-Methoxyphenyl)-1-penten-3-one (CAS No 104-27-8), when used as a fragrance ingredient.

445. Methyl *trans*-2-butenolate (CAS No 623-43-8), when used as a fragrance ingredient.

446. 7-Methylcoumarin (CAS No 2445-83-2), when used as a fragrance ingredient.

447. 5-Methyl-2,3-hexanedione (CAS No 13706-86-0), when used as a fragrance ingredient.

448. 2-Pentylidenecyclohexanone (CAS No 25677-40-1), when used as a fragrance ingredient.

449. 3,6,10-Trimethyl-3,5,9-undecatrien-2-one (CAS No 1117-41-5), when used as a fragrance ingredient.

450. Verbena oil (*Lippia citriodora* Kunth.) (CAS No 8024-12-2), when used as a fragrance ingredient.

451. Methyleugenol (CAS No 95-15-2) except for normal content in the natural essences used and provided that the concentration does not exceed:

- (a) 0,01 % in fine fragrance
- (b) 0,004 % in eau de toilette
- (c) 0,002 % in fragrance cream
- (d) 0,001 % in rinse-off products
- (e) 0,0002 % in other leave-on products and oral hygiene products.⁽¹⁾

2. In Annex III, Part 1:

(i) In reference No 8, column b is replaced by the following:

'm- and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of o-Phenylenediamines ⁽¹⁾, with the exception of those derivatives listed *elsewhere* in this Annex

⁽¹⁾ These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1.'

(ii) Reference Nos 15b and 15c are replaced by the following:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15b	Lithium hydroxide	(a) Hair straighteners 1. General use 2. Professional use (b) pH adjuster — for depilatories (c) Other uses — as pH adjuster (for rinse-off products only)	(a) 1. 2 % ⁽¹⁾ by weight 2. 4,5 % ⁽¹⁾ by weight	(b) pH value not to exceed pH 12,7 (c) pH value not to exceed pH 11	(a) 1. Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2. For professional use only Avoid contact with eyes Can cause blindness (b) Contains alkali Keep out of reach of children Avoid contact with eyes
15c	Calcium hydroxide	Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) pH adjuster — for depilatories (c) Other uses (e.g. pH adjuster, processing aid)	(a) 7 % by weight of calcium hydroxide	(b) pH value not to exceed pH 12,7 (c) pH value not to exceed pH 11	(a) Contains alkali Avoid contact with eyes Keep out of reach of children Can cause blindness (b) Contains alkali Keep out of reach of children Avoid contact with eyes

⁽¹⁾ The concentration of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits given in column d.'

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(iii) Reference No 16 is replaced by the following:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
16	1-Naphthol (CAS No 90-15-3) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction

(iv) Reference No 66 is inserted as shown in the following table:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
66	Polyacrylamides	(a) Body-care leave-on products (b) Other cosmetic products		(a) Maximum residual acrylamide content 0,1 mg/kg (b) Maximum residual acrylamide content 0,5 mg/kg	

3. In Annex III, Part 2:

Reference Nos 1 to 62 are inserted as shown in the following table:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
1	Basic Blue 7 (CAS No 2390-60-5)	Non-oxidising colouring agents for hair dyeing	0,2 %		Can cause allergic reaction	30.9.2004
2	2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004

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Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
3	4-Amino-3-nitrophenol (CAS No 610-81-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
4	2,7-Naphthalenediol (CAS no 582-17-2) and its salts	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %		30.9.2004
5	m-Aminophenol (CAS no 591-27-5) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
6	2,6-Dihydroxy-3,4-dimethylpyridine (CAS No 84540-47-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
7	4-Hydroxypropylamino-3-nitrophenol (CAS No 92952-81-3) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 5,2 % (b) 2,6 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2,6 %	(a) (b) Can cause allergic reaction	30.9.2004
8	6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts	Non-oxidising colouring agent for hair dyeing	3,0 %		Can cause allergic reaction	30.9.2004
9	HC Blue No 11 (CAS No 23920-15-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
10	Hydroxyethyl-2-nitro-p-toluidine (CAS No 100418-33-5) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	(a) (b) Can cause allergic reaction	30.9.2004

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Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
11	2-Hydroxyethylpicramic acid (CAS No 99610-72-7) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	(a) (b) Can cause allergic reaction	30.9.2004
12	p-Methylaminophenol (CAS No 150-75-4) and its salts	Oxidising colouring agent for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004
13	2,4-Diamino-5-methylphenoxyethanol (CAS No 141614-05-3) and its salts	Oxidising colouring agent for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004
14	HC Violet No 2 (CAS No 104226-19-9) and its salts	Non-oxidising colouring agent for hair dyeing	2,0 %			30.9.2004
15	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts	Non-oxidising colouring agent for hair dyeing	3,0 %		Can cause allergic reaction	30.9.2004
16	HC Blue No 12 (CAS No 104516-93-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1,5 % (b) 1,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,75 %	(a) (b) Can cause allergic reaction	30.9.2004
17	2,4-Diamino-5-methylphenetol (CAS No 141614-04-2) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
18	1,3-Bis-(2,4-diaminophenoxy)propane (CAS No 81892-72-0) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004

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Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
19	3-Amino-2,4-dichlorophenol (CAS No 61693-42-3) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
20	Phenyl methyl pyrazolone (CAS No 89-25-8) and its salts	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
21	2-Methyl-5-hydroxyethylaminophenol (CAS No 55302-96-0) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
22	Hydroxybenzomorpholine (CAS No 26021-57-8) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause allergic reaction	30.9.2004
23	1,7-Naphthalenediol (CAS No 575-38-2) and its salts	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %	Can cause allergic reaction	30.9.2004
24	HC Yellow No 10 (CAS No 109023-83-8) and its salts	Non-oxidising colouring agents for hair dyeing	0,2 %			30.9.2004
25	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3) and its salts	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %	Can cause allergic reaction	30.9.2004
26	HC Orange No 2 (CAS No 85765-48-6) and its salts	Non-oxidising colouring agents for hair dyeing	1,0 %			30.9.2004
27	HC Violet No 1 (CAS No 82576-75-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004

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Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
28	3-Methylamino-4-nitro-phenoxy-ethanol (CAS No 59820-63-2) and its salts	Non-oxidising colouring agents for hair dyeing	1,0 %			30.9.2004
29	2-Hydroxy-ethylamino-5-nitro-anisole (CAS No 66095-81-6) and its salts	Non-oxidising colouring agents for hair dyeing	1,0 %			30.9.2004
30	2-Chloro-5-nitro-N-hydroxy-ethyl-p-phenylenediamine (CAS No 50610-28-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
31	HC Red No 13 (CAS No 29705-39-3) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,5 % (b) 2,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,25 %		30.9.2004
32	1,5-Naphthalenediol (CAS No 83-56-7) and its salts	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %		30.9.2004
33	Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine) (CAS No 128729-30-6) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %	Can cause allergic reaction	30.9.2004
34	o-Aminophenol (CAS No 95-55-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
35	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
36	2,4-Diaminophenoxyethanol (CAS No 70643-19-5) and its salts	Oxidising colouring agents for hair dyeing	4,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2,0 %		30.9.2004
37	2-Methylresorcinol (CAS No 608-25-3) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
38	4-Amino-m-cresol (CAS No 2835-99-6) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
39	2-Amino-4-hydroxyethylaminoanisole (CAS No 83763-47-7) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
40	3,4-Diaminobenzoic acid (CAS No 619-05-6) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
41	6-Amino-o-cresol (CAS No 17672-22-9) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
42	2-Aminomethyl-p-aminophenol (CAS No 79352-72-0) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
43	Hydroxyethylamino-methyl-p-aminophenol (CAS No 110952-46-0) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
44	Hydroxyethyl-3,4-methylenedioxyaniline (CAS No 81329-90-0) and its salts	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004

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Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
45	Acid Black 52 (CAS No 16279-54-2) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
46	2-Nitro-p-phenylenediamine (CAS No 5307-14-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,3 % (b) 0,3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,15 %		30.9.2004
47	HC Blue No 2 (CAS No 33229-34-4) and its salts	Non-oxidising colouring agents for hair dyeing	2,8 %			30.9.2004
48	3-Nitro-p-hydroxyethylaminophenol (CAS No 65235-31-6) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 6,0 % (b) 6,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 3,0 %		30.9.2004
49	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
50	HC Red No 10 + HC Red No 11 (CAS No 95576-89-9 + 95576-92-4) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
51	Yellow No 6 (CAS No 104333-00-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
52	HC Yellow No 12 (CAS No 59320-13-7) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 1,0 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %		30.9.2004

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
53	HC Blue No 10 (CAS No 173994-75-7) and its salts	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
54	HC Blue No 9 (CAS No 114087-47-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
55	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 % (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %		30.9.2004
56	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 % (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %		30.9.2004
57	Basic Blue 26 (CAS No 2580-56-5) (CI 44045) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 % (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %		30.9.2004
58	Acid Red 33 (CAS No 3567-66-6) (CI 17200) and its salts	Non-oxidising colouring agents for hair dyeing	2,0 %			30.9.2004
59	Ponceau SX (CAS No 4548-53-2) (CI 14700) and its salts	Non-oxidising colouring agents for hair dyeing	2,0 %			30.9.2004
60	Basic Violet 14 (CAS No 632-99-5) (CI 42510) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non-oxidising colouring agents for hair dyeing	(a) 0,3 % (b) 0,3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,15 %		30.9.2004

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Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
61	Musk xylene (CAS no 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1,0 % in fine fragrance (b) 0,4 % in eau de toilette (c) 0,03 % in other products			28.2.2003
62	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1,4 % in fine fragrance (b) 0,56 % in eau de toilette (c) 0,042 % in other products			28.2.2003'

4. In Annex VII, Part 1

Reference Nos 26 and 27 are inserted as shown in the following table:

Reference number	Substance	Maximum authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
26	Dimethicodiethylbenzalmalonate (CAS No 207574-74-1)	10 %		
27	Titanium dioxide	25 %		

EXHIBIT 3

COMMISSION DIRECTIVE 2004/88/EC

of 7 September 2004

amending Council Directive 76/768/EEC concerning cosmetic products for the purpose of adapting Annex III thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers,

Whereas:

- (1) As the risk assessment had not been completed in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances⁽²⁾, the period of inclusion in part 2 of Annex III to Directive 76/768/EEC for musk xylene and musk ketone was extended until 30 September 2004.
- (2) On 8 January 2004, the Scientific Committee on Toxicity, Ecotoxicity and the Environment adopted an opinion on the results of the risk assessment of musk xylene and musk ketone that was carried out in accordance with Regulation (EEC) 793/93.
- (3) The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP) has confirmed that musk xylene can be safely used in cosmetic products, excluding oral care products, up to a maximum concentration in the final product of 1 % in fine fragrance, 0,4 % in eau de toilette and 0,03 % in other products and that musk ketone can be safely used in cosmetic products, excluding oral care products, up to a maximum concentration in the final product of 1,4 % in fine fragrance, 0,56 % in eau de toilette and 0,042 % in other products.

(4) It is therefore necessary to include musk xylene and musk ketone in part 1 of Annex III to Directive 76/768/EEC while the corresponding entries in part 2 of that Annex should be deleted.

(5) Directive 76/768/EEC should therefore be amended accordingly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 76/768/EEC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 October 2004 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 7 September 2004.

For the Commission

Olli REHN

Member of the Commission

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2003/83/EC (OJ L 238, 25.9.2003, p. 23).

⁽²⁾ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

ANNEX

Annex III to Directive 76/768/EEC is amended as follows:

1. In part 2, the entries under reference numbers 61 and 62 are deleted.
2. In part 1, the following entries are added as reference numbers 96 and 97:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
96	Musk xylene (CAS No 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1,0 % in fine fragrance (b) 0,4 % in eau de toilette (c) 0,03 % in other products		
97	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1,4 % in fine fragrance (b) 0,56 % in eau de toilette (c) 0,042 % in other products		

EXHIBIT 4

DRAFT- CTFA

GUIDELINES FOR COSMETIC

GOOD MANUFACTURING

PRACTICES

Approved by the Quality Assurance Committee

March 4, 1999

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Process Water

Adequate control should be maintained over process water, which is one of the most critical raw materials used in aqueous cosmetic products. Procedures should be established which ensure that water used in the manufacture of cosmetic products (whether untreated or treated by such means as deionization, distillation, or reverse osmosis) is:

- Supplied to manufacturing by means of systems which are constructed in a manner designed to prevent microbial contamination, and which are cleaned and sanitized according to appropriate frequencies and methods.
- Appropriately monitored and tested in order to verify conformance with applicable chemical, physical, and microbiological specifications.

CONTROL OF PRODUCTION

Procedures should be established which are designed to assure that manufacturing and packaging of cosmetic products is governed by effective systems and controls, such that opportunities for contamination are minimized and that production output consistently conforms to established control limits and specifications.

Two specific elements should be considered basic to effective production control.

- **Product Formula.** Each product should have a specific master (official) formula, in order to assure that each batch of product has the intended composition and to assure uniformity from batch to batch. The product formula should include:
 - Product identification (name and formula number and/or code).
 - Approval by a responsible person.
 - A complete list of raw materials, designated by name and/or code.
 - The weight, measure, or percent of each raw material used.
 - Statement of the total weight, measure, or percent.
 - Provisions for any appropriate variations and adjustments.
 - Specifications governing specific concerns, such as special

handling needs, safety precautions, microbiological requirements, and environmental measures.

- **Manufacturing Procedures.** Each product formula should be accompanied by procedures which define all steps for ensuring correct and consistent manufacturing and packaging. All processing elements should be described, including as applicable:
 - Start/stop times.
 - Mixing temperatures and speeds.
 - Addition of the specified weight/measure/percent of the correct raw materials.
 - Procedures for line startup and line clearance.
 - Special notations and precautions regarding such concerns as handling, safety, microbiology, and the environment.

In addition, production control measures should be established which are designed to ensure:

- Performance of processing and ancillary activities by qualified personnel.
- Identification of major processing equipment so as to clearly indicate what product is being produced.
- Proper performance of processing and control equipment.
- Adequate in-process controls at appropriate intervals.
- Proper control and disposition of in-process materials and products.
- Adequate control over labels:
 - Issuance of correct and up-to-date labels.
 - In-process monitoring of label use so as to prevent mixups.
 - Destruction of excess labels bearing lot or control numbers.
 - Adequate controls to ensure separation of different labels.
- Storage and handling of containers and equipment in a manner adequate to prevent mixups and contamination of products and materials.
- Labeling, holding, and disposition of rejected lots.

Control of Finished Products

Procedures should be established which ensure that all finished products are verified as conforming to established specifications and approved by a designated authority before they are released for packing and distribution.

Controls should be in place which ensure that all finished product containers are correctly and permanently labeled, and that they bear a unique identification (such as a lot/batch code) which enables traceability to manufacturing and distribution records.

-

NONCONFORMING MATERIAL CONTROL

Procedures should be established that ensure all nonconforming materials are controlled, stored, and disposed so as to prevent inadvertent use or release. Such procedures should encompass raw materials, packaging materials (including labels), in-process materials, and finished products.

Nonconforming materials should be identified as to their identity, order/lot/batch designation, and quality status. They should be segregated from conforming items by such means as

- conspicuous labeling of all offending containers or pallets,
- placement into designated quarantine areas, and/or
- assigning a suitably protected status within computerized stock control systems.

Any decision to use or release nonconforming materials (either "as is" or after rework) should be systematically reviewed and formally approved by involved authorized personnel, fully documented, and communicated to all involved or impacted areas. Reworked materials should be re-verified in order to ensure their acceptability.

It is important to ensure that final physical disposition of nonconforming materials and other unusable items (such as obsolete labels) is carried out in a timely and safe manner.

WAREHOUSING AND DISTRIBUTION CONTROL

EXHIBIT 5

CTFA LABELING MANUAL

A Guide to Cosmetic and OTC Drug
Labeling and Advertising

EIGHTH EDITION 2006



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Manufacturers of OTC and cosmetic-drugs that want to use an NDC number should obtain a copy of the current Drug Registration and Listing System (DRLS) booklet and registration forms from the FDA's Web site www.fda.gov or from CTFA.

Batch Coding

Batch codes are numbers that enable parties to identify the batch in which a product was manufactured. The batch code serves as an easy means of identification should a recall of the product or an investigation be required. In the U.S., inclusion of batch codes in labeling is optional for cosmetics. For drug products, however, batch codes are mandatory in accordance with Current Good Manufacturing Practices for Drugs. (21 C.F.R. Part 210.)

Additional Labeling Requirements Imposed by FDA Monographs

The FDA drug monograph process, described in detail in Chapter 13, sets up specific labeling requirements for categories of OTC drugs, including cosmetic-drugs. Each monograph will include specific labeling requirements applicable only to products it covers; for example, the final monograph on sunscreen products will contain specific requirements with respect to SPF numbers, directions for children under a certain age, etc.

When an OTC drug monograph is made final, it is published as a final rule or new regulation in 21 C.F.R. Part 330 et seq. A product covered by a final monograph must conform to the terms of the monograph, or it will require an FDA pre-market approved New Drug Application (NDA). Drug products and cosmetic-drug products must conform to the terms of the monograph and the required OTC drug labeling requirements for format and content. (See Chapter 13, "The OTC Drug Review Process," for specific product categories and labeling requirements.)

Label Separation Policy

In its comments to various proposed monographs, CTFA has argued that because the jurisdiction of the OTC monograph process extends only to drug products and drug claims, cosmetic claims cannot be regulated by the monographs. The FDA replied that cosmetic claims would be permissible on the label of a cosmetic-drug if they were placed "somewhere else in the labeling" of the product. This policy came to be

known as the "label separation policy." The effect of the label separation policy, once a final monograph is published, is that the cosmetic claims of a cosmetic-drug product cannot be placed near the labeling information required by the OTC monograph. To date, the agency has refused to eliminate or modify this policy.

Warning Statements

The drug regulations also recommend or require warning statements for specific drug products. The regulations that are of particular importance to manufacturers of cosmetic-drugs are:

Section 330.1(g) requires that all drug products contain the following warnings, as applicable, regarding accidental ingestion by children:

"Keep out of reach of children." [highlighted in bold type]

For the labeling of drugs used by oral administration:

"In case of overdose, get medical help or contact a Poison Control Center right away."

For labeling of drugs used topically, rectally, or vaginally and not intended for oral ingestion:

"If swallowed, get medical help or contact a Poison Control Center right away."

For labeling of drugs used topically and intended for oral use:

"If more than used for" [insert intended use, e.g., pain]
"is accidentally swallowed, get medical help or contact a Poison Control Center right away."

Miscellaneous Drug Product Warnings

Section 369.20 "recommends" several warning and caution statements for certain drugs. In addition to those warnings listed here, it is recommended that one consult 21 C.F.R. 369.20 for more current information.

For all antiperspirants:

"Do not apply to broken skin. If a rash develops, discontinue use."